

ANSI/HPS N43.10-2001

**American National Standard –**

**Safe Design and Use of Panoramic,  
Wet Source Storage Gamma Irradiators (Category IV) and  
Dry Source Storage Gamma Irradiators (Category II)**

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American National Standards Institute, Inc.**

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## Preface

(This preface is not a part of American National Standard N43.10, Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV), and Dry Source Storage Gamma Irradiators (Category II)).

The 1950's and 1960's can be characterized as the research era for radionuclide applications. Based on this research, a number of commercial gamma irradiators started operation in the early 1960's. Their number has been increasing with source storage capacity of individual irradiators reaching the multi-petabequerel, (multi-megacurie) range.

Gamma irradiators are used for a variety of purposes in research, industry, and other fields. Typical uses are:

1. Sterilization or microbial reduction in medical and pharmaceutical supplies and consumer products.
2. Microbial reduction and disinfestation of food products.
3. Radiation effects studies.
4. Chemical and polymer synthesis and modifications.
5. Insect eradication through sterile male release programs.

The number and types of irradiators supporting these and other applications are continually growing. Source requirements for any particular irradiator may vary from a few curies to several million curies. Irradiator designs can be many and varied to suit individual needs; therefore, it is essential to establish basic criteria to ensure a high standard of radiation safety in the design and use of irradiators, but in a way which does not unnecessarily restrict the logical use and growth of radionuclide applications.

This standard sets forth basic safety standards which are recommended in irradiator design and use. Its use by Regulatory Authorities, relative to the review of radionuclide applications, is encouraged. This standard is an industry consensus and does not take precedence over applicable federal or state regulations.

Because of the variety of designs, four general categories of irradiators have been established to facilitate preparation of standards. Separate standards establish the criteria to be used in the design, fabrication, installation, use, and maintenance for each irradiator category.

The categories are as follows:

*Category I* - Self-contained, dry source storage irradiators. American National Standard N43.7.

An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is not physically possible in its designed configuration.

*Category II* - Panoramic, dry source storage irradiator. American National Standard N43.10.

A controlled human access irradiator in which the sealed source is contained in a dry container constructed of solid materials, and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

*Category III* - Self-contained, wet source storage irradiator. American National Standard N43.15.

An irradiator in which the sealed source is contained in a storage pool (usually containing water), the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is physically restricted in its designed configuration and proper mode of use.

*Category IV* - Panoramic, wet source storage irradiator. American National Standard N43.10.

A controlled human access irradiator in which the sealed source is contained in a storage pool (usually containing water), and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

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## 1. Scope

This standard applies to panoramic, wet source storage gamma irradiators (Category IV) and dry source storage gamma irradiators (Category II) that contain sealed gamma emitting sources for the irradiation of objects or materials. The standard establishes the criteria to be used in the proper design, fabrication, installation, use, and maintenance of these irradiators which will ensure a high degree of radiation safety. This standard is not a substitute for regulations. Nothing in this standard relieves persons from complying with applicable Federal and State requirements governing the use of these facilities to irradiate products, for example, foodstuff and medical devices.

## 2. Definitions

The definitions and terms contained in this standard, or in other American National Standards referred to in this document, are not intended to embrace all legitimate meanings of the terms. They are applicable only to the subject treated in this standard.

This standard applies to irradiator designs produced after the date of this publication. Existing irradiator owners may wish to review this standard for possible upgrades.

**Accessible Surface** - that surface of the irradiator to which human access is possible without the use of tools or without penetration of the structural radiation shield.

**Authorized Personnel** (*Authorized person*) - those individuals authorized by the pertinent regulatory or controlling authority to:

- operate and control access to the irradiator,
- perform periodic contamination detection tests on the irradiator,
- install, maintain, and service the irradiator.

**Capsule** - protective envelope used for

prevention of leakage of radioactive material from a sealed source.

**Contaminated Material** - any material or object other than a sealed source that contains a radioactive substance (or substances) in average concentration or total quantity in excess of the limits established by the pertinent regulatory or controlling authority.

**Fully Shielded** - the condition in which the source is stored so that the radiation level in the radiation room does not exceed the levels specified in Part 5.4.2 of this standard.

**Fully Vented** - a design characteristic of hollow tools, tubes, or control rods, that allows air to escape from the tool at a rate sufficient to allow water to flood the immersed section as it enters the water.

**Installation of Irradiator** - the construction, source loading, and the commissioning of an irradiator.

**Interlock** - see *Safety Interlock*.

**Irradiator** - a device or facility which contains and uses sealed sources for the irradiation of objects or materials. See Panoramic Wet Source Storage Irradiator or Panoramic Dry Storage Irradiator.

**Irradiator Shut Down** - stops conveyors, returns the source to the fully shielded position.

**Licensee** - individual or organization to whom the pertinent regulatory authority has issued a license authorizing receipt, possession, use, and/or transfer of sealed sources and operation of an irradiator.

**Operator** - an authorized person who controls the use of the irradiator.

**Panoramic** - the volume undergoing irradiation is large enough to accommodate a reference man as defined in ICRP 23.

**Panoramic Wet Source Storage Irradiator** - a controlled human access irradiator in which the sealed source is contained in a storage pool (usually containing water), and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation room that is maintained inaccessible during use by interlocked controls.

**Panoramic Dry Source Storage Irradiator** - a controlled human access irradiator in which the sealed source is contained in a dry storage container constructed of solid materials, and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation room that is maintained inaccessible during use by interlocked controls.

**Product** - the objects or materials which are intentionally irradiated in a commercial or research process.

**Product Positioning System** - the means by which the product to be irradiated is conveyed around the sealed source under the source-in-use condition. (Also referred to as conveyor.)

**Qualified Expert** - a person having the knowledge, training, and experience necessary to perform a task in his/her field or specialty, in a competent and proficient manner.

**Quality Assurance** - all those planned and systematic actions necessary to provide adequate confidence that an item or a facility will perform satisfactorily in service.

**Quality Control** - those quality assurance actions which provide a means to control, measure and document the characteristics of an item, process, or facility to establish requirements.

**Radiation Room** - that region of the irradiator that is enclosed by radiation shields and is made inaccessible when the source is in use.

**Radiation Shields** - the materials which have as their primary function the attenuation of radiation emitted by the sealed source to acceptable

levels.

**Restricted Area** - that region of the irradiator to which human access is controlled for radiation safety purposes.

**Safety Interlock** - a device for precluding exposure of an individual to a hazard either by preventing entry to the hazardous area or by automatically removing the hazard.

**Safety-Related Service** - any service work which could affect the radiation safety of an irradiator such as source transport, source loading, replenishment, removal, or redistribution; modification or service to safety interlocks; or modification to the radiation shields which could result in elevated radiation levels.

**Sealed Source** - radioactive material sealed in a capsule, designed to maintain structural and dimensional integrity under the conditions of intended use, and to prevent dispersion of the contaminated radioactive material under plausible accident conditions. See also *Source Array*.

**Shall** - indicates a recommendation that is necessary to meet the standards of protection of this document.

**Should** - indicates an advisory recommendation that is to be applied when practicable.

**Source** - see *Sealed Source*.

**Source Array** - an assemblage of sealed sources in an array utilized in an irradiator.

**Source Holder** - that component of the irradiator into which the source is positioned, including any retaining screws, pins, clips, etc.

**Source in Use** - that status of an irradiator during which the sealed source is not fully shielded.